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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,683	11/25/2003	Richard B. Roth	SEQ-4072-UT	3204

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EXAMINER	
SITTON, JEHANNE SOUAYA	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/723,683	ROTH ET AL.	
	Examiner	Art Unit	
	Jehanne S. Sitton	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-64* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-20, 51-53 (in part), and 59-60, drawn to a method for identifying a subject at risk of breast cancer, detecting breast cancer, and selecting a subject that will respond to treatment of breast cancer, via the detection of polymorphic variation, classified in class 435, subclass 6.

II. Claims 21-26, drawn to a method for identifying a polymorphic variation associated with breast cancer proximal to an incident polymorphism, classified in class 435, subclass 6.

III. Claims 27-29, drawn to an isolated nucleic acid comprising a polymorphic variation, classified in class 536, subclass 23.1.

IV. Claim 30, drawn to a polypeptide, classified in class 530, subclass 350.

V. Claims 31-38, drawn to a method for identifying a candidate test molecule that modulates cell proliferation, classified in class 514, subclass 1.

VI. Claims 39-41, drawn to a method of treating breast cancer by contacting one or more cells with a nucleic acid, such as RNA, classified in class 536, subclass 24.5.

VII. Claims 42-50, drawn to a method of treating breast cancer comprising detecting a polymorphic variation, classified in class 514, subclass 1.

VIII. Claims 51 (in part), 54, and 55, drawn to a method of preventing breast cancer by detecting a polymorphic variation and administering a breast cancer preventative such as a hormone, classified in class 424, subclass 562.

IX. Claims 56-58, drawn to a method of targeting information, classified in class 702, subclass 20.

X. Claim 61-62, drawn to a composition comprising a breast cancer cell and an antibody, classified in class 424, subclass 130.1.

XI. Claims 63-64, drawn to a composition comprising a breast cancer cell and a nucleic acid, such as siRNA, classified in class 536, subclass 24.5.

2. Additionally, each group named above is subject to further restriction. Applicant is required to further elect a specific SEQ ID NO and to further elect a specific polymorphism or combination of polymorphisms to which the claims will be limited. This is NOT an election of species. The nucleotide sequences are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the

applicant... to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a). It is noted that searching more than one of the claimed patentably distinct sequences and variants represents a serious burden for the office. The search for each sequence and variant are not coextensive and are required to be searched separately in both computer databases as well as nucleotide variant databases such as dbSNP.

It is noted that any claim which specifically lists only a non elected sequence or variant will be withdrawn from consideration as being drawn to a non elected invention. Claims which are drawn to sequences and/or variants in the alternative and which include the elected sequence and/or variant, will be searched and examined with regard to the elected invention.

3. The inventions are distinct, each from the other because of the following reasons:

The inventions of groups I-II, VII, VIII, and IX are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods include steps of determining polymorphisms, however, the methods of group I of identifying a subject at risk of breast cancer, vs group II, a method of identifying an incident polymorphism, vs group VII, a method of treating breast cancer, vs group VIII, a method of preventing breast cancer, vs group IX, a method of targeting information, are not coextensive in scope as each method is directed to different steps to perform the method, ie: analysis of breast cancer, analysis of another proximal polymorphism, treatment based on results of genotype analysis, prevention

based on results of genotype analysis, and directing information. Further, the methods are not obvious variants. Each method has a materially different mode of design, mode of operation, function, and effect. A search for each of the patentably distinct process presents a serious search burden as the searches are not coextensive. Art directed to methods of identifying a risk of breast cancer (group I), would not necessarily provide any information regarding proximal polymorphism, treatment, prevention, or information targeting, and vice versa.

The inventions of groups I, II, and IX are unrelated to the inventions of groups V and VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different designs, modes of operation and effects.

The inventions of groups I, II, and IX are unrelated to the inventions of groups IV, and X-XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different products are not disclosed as capable of use with the methods of groups I or II and the different inventions have different designs, modes of operation and effects.

The inventions of group III and groups I, II, VI, VII, VIII, & IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the products can be

used to encode polypeptides or to detect expression, which are not required to practice the method of Group I or IX. Further, the product of group III is not required to practice the method of group II. The method of detecting a proximal polymorphism is not dependent on the detection of the incident polymorphism. The search for each group presents a serious search burden as the searches for each are not coextensive in scope. Art relating to polynucleotides would not necessarily provide any descriptive information regarding breast cancer and vice versa.

The inventions of groups III, IV, X, and XI are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of group III is composed of deoxyribonucleotides linked by phosphodiester bonds and assumes the form of a double helix. The polypeptide of group IV is composed of amino acids linked by peptide bonds and can assume complex tertiary structures. While the compositions of groups X-XI each comprise a breast cancer cell, they additionally include structurally and functionally distinct components, such as a nucleic acid or an antibody (which composed of amino acids linked by peptide bonds, antibodies are glycosylated and their tertiary structure is unique, where four subunits [2 light chains and 2 heavy chains] associate via disulfide bonds into a Y-shaped symmetric dimer, and is structurally and functionally distinct from a nucleic acid). The products of groups III, IV, X, and XI can be used in materially different processes, for example the DNA of group III can be used in hybridization assays, the polypeptide of group IV can be used to make a fusion protein with an enzymatic function, the composition of group X can be used in methods of screening for nucleic acids for therapy, the composition of group XI can be used to induce an immune response. Consequently, the reagents, reaction conditions, and reaction parameters required to make and use each invention are different. Therefore, the inventions of

groups III, IV, and X-XI are patentably distinct from each other. The search for each of groups III, IV, and X-XI presents a serious search burden as the searches for each are not coextensive in scope. The inventions have different status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is a search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies. Furthermore, antibodies which bind to an epitope of a polypeptide of group may be known even if the polypeptide is novel. Further, the compositions of group X include additional components which are not required for either groups III or IV and a search of any of these groups would not necessarily provide art for the compositions of group X. Searching, therefore is not coextensive and presents a serious burden.

The invention of group III is unrelated to the invention of group V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the products are not used in the method of group V and the different inventions have different designs, modes of operation and effects.

The invention of group IV is unrelated to the inventions of groups I, II, V, VI, VII, VIII, & IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the products is not used in the methods of groups I, II, V, VI, VII, VIII, or IX and the different inventions have different designs, modes of operation and effects.

The inventions of groups V-VII are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods include steps of treatment or modulation, however, the different methods: that is, group V, of identifying a modulator of cell proliferation, vs group VI, a method of treatment using nucleic acid, vs group VII, a method of treatment by detecting a polymorphism and treating with surgery or chemotherapy, are not coextensive in scope as each method is directed to different steps requiring different reagents and parameters. Further, the methods are not obvious variants. Each method has a materially different mode of design, mode of operation and function. A search for each of the patentably distinct process presents a serious search burden as the searches are not coextensive. Art directed to each of the different modes of treatment or modulation would not necessarily provide any information on polymorphism or any of the other claimed modulators.

The inventions of groups V-VI are unrelated to the inventions of groups VIII-XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06).

In the instant case, the different inventions have different designs and modes of operation and effects.

The inventions of groups VII-VIII are unrelated to the inventions of groups X-XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different designs and modes of operation and effects.

4. Claim 42 is generic to the disclosed patentably distinct subgenus and species in claims 47-49. The subgenus and species are independent or distinct because they are drawn to materially different processes and compounds. Applicant is required under 35 U.S.C. 121 to elect a single disclosed subgenus from claim 47, and to further elect species in claim 48 and 49 (if combinations in claim 45 is elected), as appropriate to the subgenus elected in claim 47, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. Claim 51, directed to detection, is generic to the disclosed patentably distinct species in claim 53. The species are independent or distinct because they are drawn to materially different processes. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. Claim 51, directed to prevention, is generic to the disclosed patentably distinct subgenus and species in claims 54 and 55. The species are independent or distinct because they are drawn to materially different processes and compounds. Applicant is required under 35 U.S.C. 121 to elect a single disclosed subgenus from claim 54, and to further elect a corresponding species in claim 55, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

8. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

9. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

10. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jehanne Sitton
Primary Examiner
Art Unit 1634
6/12/06